

Claims 1-26 were rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between steps. Specifically, the claims do not set forth the steps for stabilizing the ascorbic acid.

Claim Rejections 35 –U.S.C. § 103

Claims 1-26 were rejected under 35 U.S.C. § 103(a) as obvious over Schinitzky, et al. (U.S. Patent No. 4,938,969), in view of Murad (U.S. Patent No. 5,804,594), and Herstein (U.S. Patent No. 5,902,591).

Double Patenting

Claims 1-26 were rejected under the judicial Doctrine of Obviousness-Type Double Patenting in light of U.S. Patent No. 6,217,914 and provisionally over claims 32-51 of U.S. Patent Application No. 09/732,385.

During prosecution of related U.S. Patent Application No. 09/732,385, the Examiner and the Applicant agreed that the term "pretreated" was defined in Applicant's specification. It was further agreed to adopt the definition as set forth in Applicant's specification. Applicant respectfully submits that the same is true in the instant case and requests adoption of the definition of the term "pretreated" as found in Applicant's specification in the paragraph beginning on page 6 and continuing on page 7, namely:

It has found that ascorbic acid-based topical formulations in which a substantial portion of the ascorbic acid has been "pretreated" exhibit particularly good storage stability. As noted above, for the purposes of this application, pretreated ascorbic acid refers to ascorbic acid that has been dissolved in water at a relatively high temperature to form a concentrated ascorbic acid solution. Typically, the ascorbic acid is dissolved in water at between about 60 to about 90°C (e.g., between about 75 to about 80°C) to form a concentrated solution which contains at least about 20% (w/v) ascorbic acid. During this pretreatment, the ascorbic acid is dissolved in the acid form, i.e., the resulting solution will have a relatively low pH (circa 2.0-2.5). After dissolution, the concentrate is generally heated for an additional period of time (e.g., 0.25 to 1.0 hour) and cooled to below about 40°C before being

incorporated into the final formulation. If the pretreated concentrate is to be stored prior to formulation, it is preferably stored at room temperature or below (e.g., about 3 to about 20°C) and/or under conditions which exclude oxygen-containing gases such as air (e.g., in a sealed container or blanketed with an inert gas such as argon or nitrogen). In the present compositions, commonly at least about 10% of the ascorbic acid present has been pretreated. Typically, no more than about 50% of the ascorbic acid present has been pretreated. This allows the enhanced stability properties to be obtained while minimizing the additional processing steps and cost associated with the pretreatment of the ascorbic acid.

The definition above is materially identical to the definition accepted in the parent case. Applicant respectfully believes that use of the defined term "pretreated" in the claims brings claims 1-26 into compliance with 35 U.S.C. § 112, first and second paragraphs, and also overcomes the claim rejections based on 35 U.S.C § 103.

Claims 1-26 were rejected under the judicial Doctrine of Obviousness-Type Double Patenting in light of U.S. Patent No. 6,217,914 and provisionally over claims 32-51 of U.S. Patent Application No. 09/732,385. The official Action provides that a timely filed Terminal Disclaimer pursuant to 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on non-statutory double patenting. Accordingly, Applicant submits herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c).

Applicant respectfully believes that claims 1-26 are allowable. Applicant respectfully requests reconsideration by the Examiner, withdrawal of claim rejections, and advancement of the claims to allowance.

CONCLUSION

The present paper constitutes a complete response to the official Action mailed December 18, 2001. Applicant respectfully requests that the remarks herein be considered to a favorable conclusion of the case. Applicant believes that the case is in condition for allowance and earnestly requests a Notice of Allowance at the earliest possible time. No fees are believed due with this response. Should the Examiner have any questions, comments or

suggestions that would expedite the prosecution of the present case to allowance, Applicant's undersigned representative earnestly requests a telephone conference.

Respectfully submitted,

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